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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,280	12/21/2006	John C. Hutton	2848-56-PUS	4524

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SHERIDAN ROSS PC
1560 BROADWAY
SUITE 1200
DENVER, CO 80202

EXAMINER	
CARLSON, KAREN C	
ART UNIT	PAPER NUMBER
1656	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,280	HUTTON ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,7 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6, 7, and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 24, 2009 has been entered.

Claims 6, 7, and 11, drawn to a method of detecting diabetes via IGRP detection of auto-antibodies, are currently pending and are under examination.

Benefit of priority is to September 22, 2003.

Maintenance of Rejections:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6, 7, and 11 are again rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility.

At page 22, in Example 2, the specification states:

EXAMPLE 2

Test for antibodies to IGRP.

IGRP was investigated as a humoral autoantigen in diabetic human subjects and NOD mice using a series of assays based either upon immunoprecipitation of 35S-labelled *in vitro* translated protein generated from reticulocyte lysates, or ELISAs based on the binding of antibodies to recombinant protein immobilized on microtiter plates or PVDF membranes. **The assays easily detected antibodies from rabbits immunized with an IGRP COOH-terminal peptide or recombinant antigen (antibody dilution l:50 to 1:8000) but**

failed to demonstrate the presence of autoantibodies in spontaneous diabetic or prediabetic samples, a high proportion of which were positive for one or more other autoantigens (insulin, GAD65 and ICA512). Other assays in which IGRP was translated *in vitro* with dog pancreatic microsomes to mimic its insertion into membranes and core glycosylation were similarly negative. Thus, any humoral autoimmune response remains to be characterized despite testing more than 100 diabetic and 50 control human subjects and 50 NOD mice at various stages of diabetes development.

At page 27, in Example 8, the specification confirms the observations of Example 2:

EXAMPLE 8

Studies with mice bearing human MHC diabetes susceptibility genes.

Autoantibody measurements have been uninformative both in the NOD mouse and new onset diabetic patients and it is conceivable that a dominant CD8 response occurs with little involvement of B-cells.

These examples show that contacting a biological sample from a mammal with an IGRP polypeptide does not detect circulating autoantibodies to IGRP in spontaneous diabetic or prediabetic samples taken from 150 diabetic mammals studied. Therefore, a method for detecting insulin dependent diabetes or susceptibility to developing insulin dependent (type I) diabetes by contacting a biological sample from a mammal and contacting the sample with IGRP and detecting autoantibodies to IGRP is inoperative.

The Declaration of John Hutton under 37 CFR 1.132 filed September 24, 2009 is insufficient to overcome the rejection of claims 6, 7, and 11 based upon inoperability as set forth in the last Office action and above because: The examples used in the declaration are not described in the instant specification. Applicants did not perform experiments in the specification to demonstrate that diabetic mammals have

autoantibodies against IGRP. Thus, one skilled in the art could not arrive at the conclusions in the declaration by reading the specification and/or performing experiments in the specification. The specification, and the experiments performed in the specification, clearly demonstrate that "any humoral autoimmune response remains to be characterized despite testing more than 100 diabetic and 50 control human subjects and 50 NOD mice at various stages of diabetes development."

Art of Record, Re-iterated:

Lieberman et al. (July 8, 2003; Identification of the β cell antigen targeted by a prevalent population of pathogenic CD8+ T cells in autoimmuune diabetes. PNAS 100(14): 8384-8388) teach that IGRP has no known function (page 8387, right col., ~1/4 from the bottom) and that it is an autoantigen targeted by pathogenic CD8+ T cells.

Hutton et al. (July 22, 2003); A pancreatic β cell-specific homolog of glucose-6-phosphatase emerges as a major target of cell-mediated autoimmunity in diabetes. PNAS 100(15): 8626-8628) cites Lieberman et al. and discusses IGRP as an autoantigen targeted cell-mediated autoimmunity in diabetes.

No Claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the

application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson whose telephone number is 571-272-0946. The examiner can normally be reached on 6:00 AM - 4:00 PM, Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen Cochrane Carlson/
Primary Examiner, Art Unit 1656